respective generic claim.

Applicants gratefully acknowledge the Examiner's indication that the last amendment rectified all of the errors in the drawings and under 35 U.S.C. §112.

Section 102 Rejection based on Palestrant

Claims 1-7, 17, 21-24, 26-29, 30-33, 37, 60-67, 69-70, and 77-79, stand rejected under 35 U.S.C. §102(b) as being anticipated by Palestrant (U.S. Patent No. 5,472,418). Palestrant discloses a vascular catheter having two or more flattened strips of flexible material attached along their side edges so as to form a collapsible outer tube. Palestrant is directed to a multi-lumen catheter, and completely fails to describe or even suggest a multiple lumen *access device* as in the present invention which integrates features and capabilities of both an introducer and a multiple lumen catheter in a single device. On page 3, lines 10-13, introducers provide an avenue for medical implements to be introduced and withdrawn from the body. The device of the present invention combines both introducer and a multiple lumen catheter in one, and requires a single insertion site with fewer complications and less risk of infection. The device of Palestrant is not capable of passing a medical implement into the body.

Moreover, independent claims 1 and 60 of the present application both provide an access device having an outer tube that does not fully collapse during insertion into the body. This is not so in Palestrant where the entire catheter designed to be fully collapsed while in the body and fluid is not flowing therethrough. Please see the discussion in col. 9, line 53 through col. 10, line 19, in Palestrant of the multiple lumen embodiment of Figs. 11 and 12, where the catheters are "fully collapsible." Moreover, there is no suggestion to have an outer tube as claimed because the collapsible design teaches away from it.

Claim 30 provides an access device with a multiple lumen sheath and a soft, flexible junction housing connected to the proximal end of the sheet, the junction housing having certain internal channels and a cavity. Palestrant discloses a catheter without a soft junction housing, and no assertion that it does include such a structure was made in any Office Action so far. In col. 6, lines 30-32, Palestrant discloses a "rigid plastic body 26" as the equivalent of the

"junction housing" of claim 30. Palestrant cannot therefore anticipate claim 30. Furtherm re, because of the aforementioned language, Palestrant does not provide any motivation to provide a soft, flexible junction housing.

Based on the above arguments, claims 1, 30, and 60 are believed allowable over Young, and so also dependent claims 2-7, 17, 21-24, 26-29, 31-33, 37, 61-67, 69-70, and 77-79 are allowable over Palestrant.

Section 102 Rejection based on Young

Claims 1-3, 17-18, 20-24, 26, 28-30, 37, 60, 62, and 75-79, stand rejected under 35 U.S.C. §102(b) as being anticipated by Young (U.S. Patent No. 5,451,206). In addition to not being an access device as described in the present application, Young also does not have a flexible wall as required by the independent claims 1 and 60. Young states that "[t]he inner layer 60 of the body portion 12 is preferably formed of a harder inner material which has the same or a higher modulus or durometer than the outer layer 58 to reduce the likelihood of septum deflection during use" (col. 9, lines 54-58). Therefore, Young does not disclose, and in fact teaches away from, the flexible wall as in claims 1 and 60. Young does not anticipate nor make obvious claims 1 and 60.

With regard to the term "flexible," applicants assert that the limitations in claim 1 and 60 are not functional, and in fact prescribe the flexibility of the wall in terms of its structural ability to move between positions. Much like saying that a strut is sufficiently long so as to bridge two points, which is not a functional limitation.

With respect to independent claim 30, the same comment made above in regard to Palestrant also applies to Young. Young discloses a "Y-shaped connector hub 16" on the proximal end of the catheter. No mention of its material properties is made, and therefore there is no disclosure or suggestion to make it soft and flexible.

Based on the above arguments, claims 1, 30, and 60 are believed allowable over Young, and so also dependent claims 2-3, 17-18, 20-24, 26, 28-29, 37, 62, and 75-79 are allowable over Young.

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Section 103 Rejection based on Palestrant and Nishijima

Claims 8-10 and 34-36, stand rejected under 35 U.S.C. §103(a) as being obvious over Palestrant in view of the Nishijima, et al. (U.S. Patent No. 5,092,846). Applicants assert that because base claims 1 and 30 are allowable as explained above, these dependent claims are also allowable. Furthermore, there is no motivation in Palestrant to include a valve device as disclosed in Nishijima, et al.

In conclusion, Applicants believe that claims 1-11, 17-18, 20-24, 26-37, 60-70, and 75-80 are in condition for allowance. Further, with the allowance of their respective base claims, which are generic, claims 12-16, 19, 25, 40, and 71-74 should be reinstated. Therefore, claims 1-37, 40, and 60-80 are believed allowable.

Respectfully submitted,

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I hereby certify that the above-identified document is being transmitted via facsimile to the Commissioner of Patents, Washington D.C. on 4/30/2002.

Signed:

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VERSION SHOWING CHANGES MADE TO CLAIMS

1. (Twice Amended) A multiple lumen access system for use in providing an entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:

an outer tube which has a distal end for introduction into the body and a proximal end, the outer tube at a particular location along its length having a cross-sectional area which does not fully collapse during insertion into the body [remains substantially unchanged];

a device lumen defined within the outer tube, the device lumen having a distal end and a proximal end, wherein medical devices may be passed through the device lumen;

an auxiliary lumen defined within the outer tube and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end;

a flexible wall located within the outer tube having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a first position, where the device lumen at the particular location has a first cross-sectional area, to multiple flexed positions, where the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen [, and wherein at the particular location any of the cross-sectional areas of the device lumen does not exceed the cross-sectional area of the outer tube].

60. (Twice Amended) A method for selectively introducing medical devices into a human body through a single entry port and for providing simultaneous auxiliary fluid access into the body, comprising:

providing a multiple lumen access device comprising:

an elongated body which has a distal end f r introduction into the body and a proximal end, the elongated body having at a particular location along its length a cross-sectional area that does not fully collapse during insertion into the body [remains substantially unchanged];

a device lumen through which medical devices may be passed defined within the elongated body, the device lumen having a distal end and a proximal end;

an auxiliary lumen defined within the elongated body and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end; and

a flexible wall located within the elongated body having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a first position, where the device lumen at the particular location has a first cross-sectional area, to multiple flexed positions, where the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen [, and wherein at the particular location any of the cross-sectional areas of the device lumen does not exceed the cross-sectional area of the elongated body];

introducing the multiple lumen access device into the body with the distal ends of the device lumen and the auxiliary lumen being positioned within a vasculature of the human body; and

flowing a medical solution through the auxiliary lumen into the vasculature in the absence of a device in the device lumen to move the flexible wall from the first position to one of the flexed position.